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ATTORNEY FOR PLAINTIFF
UNITED STATES OF AMERICA

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
MISSOULA DIVISION

UNITED STATES OF AMERICA, *ex rel*. Lenore Ludlow, **Plaintiff,** **vs.** **BELLAMAH VEIN & SURGERY, PLLC, d/b/a/ BELLAMAH VEIN CENTER, and DAVID BELLAMAH, M.D.,** **Defendants.**	**CV 18-57-M-DLC** **COMPLAINT IN INTERVENTION**

The United States of America, on behalf of the United States Department of Health and Human Services (HHS), Department of Defense, and Department of Veteran's Affairs, alleges as follows:

I. NATURE OF ACTION

1. The United States of America brings this civil enforcement action for treble damages and civil penalties under the False Claims Act, 31 U.S.C. §§ 3729-3732, and damages under common law.

2. Defendants own and operate a vascular surgery center in Missoula, Montana. Through this practice, defendants routinely performed medically unnecessary surgeries to destroy veins. To get paid for these medically unnecessary services, Defendants knowingly included false statements in the medical records of beneficiaries of government health care programs such as Medicare, Medicaid, TRICARE, and CHAMPVA.

II. THE PARTIES

3. Plaintiff in this action is the United States of America, suing on behalf of: 1) the U.S. Department of Health & Human Services ("HHS") and specifically its operating division, the Centers for Medicare & Medicaid Services ("CMS"), which administers and supervises the Medicare and Medicaid programs; 2) the U.S. Department of Defense's Defense Health Agency, acting on behalf of the TRICARE program ("Tricare"); and 3) the U.S. Department of Veteran's Affairs, which administers and supervises the CHAMPVA program ("CHAMPVA").

4. The qui tam plaintiff ("Relator"), Lenore Ludlow, was a sonographer previously employed at Defendant Bellamah Vein Center. Relator initiated this action by filing a complaint against Defendants, among others, under the qui tam provisions of the False Claims Act, 31 U.S.C. §3730(b)(1).

5. Dr. David Bellamah ("Bellamah") is a medical doctor licensed in the State of Montana, with license number MED-PHYS-LIC-9851. Bellamah primarily practices as a vascular surgeon through his business, Bellamah Vein and Surgery, PLLC.

6. Bellamah Vein and Surgery, PLLC, is a Montana personal limited liability company, which does business as Bellamah Vein Center ("BVC"). Its primary place of business is in Missoula, Montana. BVC also has an office in Kalispell, Montana. BVC is owned and operated by Bellamah.

III. JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1345 because the United States is the Plaintiff. In addition, the Court has subject matter jurisdiction over the FCA cause of action under 28 U.S.C. § 1331 and supplemental jurisdiction to entertain the common law and equitable causes of action under 28 U.S.C. §1367(a).

8. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)-(c) and 31 U.S.C. § 3732(a) because at least one of the Defendants can be found in, resides in, and transacts business in the Missoula Division of the District of Montana, and many, if not all, of the alleged acts occurred in this District.

IV. THE LAW

The False Claims Act

9. The False Claims Act, 31 U.S.C. §§ 3729-3733 ("FCA"), provides for the award of treble damages and civil penalties for, *inter alia,* knowingly causing the submission of false or fraudulent claims for payment to the United States government.

10. The FCA provides, in pertinent part, that a person who does any of the following is liable for three times the amount of damages as well as a civil penalty:

a. knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; or

b. knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.

31 U.S.C. § 3729(a)(1)(A) and (B).

11. "Knowingly," for purposes of the FCA, does not require specific intent to defraud. Instead, it means that a person:

a. has actual knowledge of the information;

b. acts in deliberate ignorance of the truth or falsity of the information; or

c. acts in reckless disregard of the truth or falsity of the information.

31 U.S.C. § 3729(b)(1).

12. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, *47103 (1999), the civil penalties were adjusted to a $5,500 minimum to $11,000 maximum for violations occurring on or after September 29, 1999. For acts which occurred after November 2, 2015, the civil penalty range increases from $11,665 to $23,331. *See* Bipartisan Budget Act of 2015, P.L. 114-74 (Nov. 2, 2015) and 28 C.F.R. § 85.5.

The Medicare Program

13. Enacted in 1965, Title XVIII of the Social Security Act, 42 U.S.C. § 1395, *et seq*., establishes the Health Insurance for the Aged and Disabled Program, commonly known as the Medicare Program or, simply Medicare.

14. The Medicare Program is comprised of four parts: Part A which provides Hospital Insurance Benefits, Part B which provides Medical Insurance

Benefits, Part C which establishes Medicare Advantage (or managed care) plans, and Part D which provides for Prescription Drug Benefits. Relevant to this complaint is Part B. Medicare Part B establishes a voluntary supplemental insurance program that pays for various medical and other health services and supplies, including physician services, physical, occupational, and speech therapy services and hospital outpatient services. *See* 42 U.S.C. §§ 1395k, 1395m, 1395x.

15. Medicare is administered by the Centers for Medicare & Medicaid Services (CMS). At all times relevant to this complaint, CMS contracted with private contractors referred to as "Medicare Administrative Contractors" (formerly known as fiscal intermediaries under Part A and carriers under Part B) to act as agents in reviewing and paying claims submitted by healthcare providers who are enrolled in Medicare. Payments are made with federal funds. *See* 42 U.S.C. §§ 1395h, 1395u; 42 C.F.R. §§ 421.3, 421.100, 421.200.

16. To participate in the Medicare program, a health care provider must enter into a provider agreement with the Secretary of HHS. 42 U.S.C. § 1395cc. This agreement requires the provider to agree to conform to all applicable statutory and regulatory requirements for reimbursement from Medicare, including the provisions of Section 1862 of the Social Security Act and Title 42 of the Code of

Federal Regulations. As part of that agreement, the provider must sign the following certification:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. The Medicare laws, regulations, and program instructions are available through the [Medicare] contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare.

Form CMS-855A; Form CMS-8551.

17. Among the legal obligations of participating providers is the requirement not to make false statements or misrepresentations of material facts concerning payment requests. 42 U.S.C. § 1320a-7b(a)(1)-(2).

18. Medicare generally reimburses only services that are "reasonable and necessary for the diagnosis or treatment of illness or injury…" 42 U.S.C. § 1395y(a)(1)(A). In submitting claims for payment to Medicare, providers must certify that the information on the claim form presents an accurate description of the services rendered and that the services were reasonable and medically necessary for the patient.

19. Federal law provides that it is the obligation of the provider of health care services to ensure that services provided to Medicare beneficiaries are

"provided economically and only when, and to the extent, medically necessary[,]" and are "[s]upported by evidence of medical necessity." 42 U.S.C. § 1320c-5(a)(1), (3).

20. The applicable Local Coverage Determination ("LCD") for Montana is L34010 published by Noridian Healthcare Solutions, Inc. This LCD provides guidance on billing vascular surgery procedures to Medicare. It states that "[t]he patient's medical record must contain a history and physical examination supporting the diagnosis of symptomatic varicose veins, and the failure of an adequate (at least 3 months) trial of conservative management." L34010, Pg. 5. In addition, "[t]he medical record must document the performance of appropriate tests, if medically necessary, to confirm the pathology of the vascular anatomy."

The Medicaid Program

21. Enacted in 1965, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq.*, also known as the Medicaid program, authorizes federal grants to states for medical assistance to low-income persons who are age 65 or younger, blind, disabled, or members of families with dependent children or qualified pregnant women or children.

22. Medicaid, jointly funded by the states and the federal government, is administered by participating states. Within broad federal rules, each state decides

who is eligible for Medicaid, the services covered, payment levels for services and administrative and operation procedures. Each state directly pays providers, with the state obtaining the federal share of the payment from accounts which draw on funds of the United States Treasury. 42 C.F.R. §§ 430.0-430.30 (1994). The Federal share of each state's Medicaid program varies state by state.

23. The State of Montana ("Montana"), through its Department of Public Health and Human Services ("DPHHS"), participates in the Medicaid program. During the years 2014-2017, Montana paid approximately 35% of Medicaid expenses, and the federal government reimbursed Montana 65% of Medicaid expenses each year.

24. By becoming a participating provider in Medicaid, enrolled providers agree to abide by the rules, regulations, policies and procedures governing reimbursement, and to keep and allow access to records and information as required by Medicaid.

25. As a condition of participation in the Montana Medicaid program, all enrolled providers "must comply with all applicable state and federal statutes, rules[,] and regulations, including but not limited to federal regulations and statutes found in Title 42 of the Code of Federal Regulations and the United States Code governing the Medicaid program[.]" Admin. R. Mont. 37.85.401.

26. All Montana Medicaid enrolled providers "must maintain records which fully demonstrate the extent, nature[,] and medical necessity of services and items provided to Montana Medicaid recipients." Admin. R. Mont. 37.85.414(1). "The records must support the fee changed or payment sought for the services and items and demonstrate compliance with all applicable requirements." *Id*.

The TRICARE Program

27. TRICARE is a managed health care program established by the Department of Defense. 10 U.S.C. §§ 1071-1110. TRICARE provides health care benefits to eligible beneficiaries which include, among others, active duty service members, retired members, and their dependents.

28. TRICARE covers the same vascular surgery procedures and treatments as Medicare. The regulatory authority implementing TRICARE provides reimbursement to health care providers applying the same reimbursement scheme and coding parameters that the Medicare program applies. 10 U.S.C. §§1079(i)(2).

29. TRICARE, like Medicare, pays only for "medically necessary services and supplies required in the diagnosis and treatment of illness or injury." 32 C.F.R. § 199.4(a)(1)(i).

30. Under the TRICARE for Life program, there are beneficiaries who are enrolled in Medicare and are still eligible for TRICARE ("dual eligible beneficiaries"). For these dual eligible beneficiaries, TRICARE is the secondary payor to Medicare and is responsible to health care providers for any amounts not covered by Medicare. TRICARE Reimbursement Manual 6010.58M, Ch. 8, § 4.4.

31. TRICARE prohibits such practices as submitting claims for services which are not medically necessary, consistently furnishing medical services that do not meet accepted standards of care, and failing to maintain adequate medical records. 32 C.F.R. §§ 199.9(b)(3)-(b)(5). TRICARE considers billing "claims which involve flagrant and persistent overutilization of services without proper regard for results, the patient's ailments, condition, medical needs, or the physician's orders" to be fraud. 32 C.F.R. § 199.9(c)(3). Such practices are deemed abusive and cause financial loss to the United States. 32 C.F.R. 199.9(b).

32. For TRICARE dual eligible beneficiaries, TRICARE follows Medicare's determinations regarding medical necessity. If services are determined not to be medically necessary under Medicare, they are not covered under TRICARE. TRICARE Reimbursement Manual 6010.58M, Ch. 8, § 2, 4.3.16 (Note).

The CHAMPVA Program

33. The Civilian Health and Medical Program of the Department of Veterans Affairs ("CHAMPVA") is a comprehensive health care program in which the Department of Veterans Affairs ("VA") shares the cost of covered health care services and supplies with eligible beneficiaries. The program is administered by Health Administration Center from its offices located in Denver, Colorado.

34. In general, the CHAMPVA program's operations are substantially similar to Medicare. For example, the CHAMPVA program covers most health care services and supplies, but only if they are medically necessary. CHAMPVA specifically excludes from coverage "[s]ervices and supplies that are not medically or psychologically necessary for diagnosis or treatment of a covered condition (including mental disorder) or injury." 38 C.F.R. § 17.272(a)(4).

V. FACTUAL ALLEGATIONS

Vascular Surgery

35. The primary procedures at issue are for the treatment of venous reflux disease, which includes varicose veins. Varicose veins are large or spidery veins in the legs. Venous reflux disease is diagnosed when a vein does not transfer blood from the lower extremities of the body back to the heart correctly.

36. Venous reflux disease can be treated with the removal or destruction of varicose veins in multiple ways. This can be done through open vein ligation and stripping, which is physically cutting and pulling a vein out of the body. Incompetent veins with reflux can also be cauterized using heat or lasers to shrink or close off the vein. Finally, sclerotherapy can be used, which involves injecting a chemical directly into a vein to permanently clot and close the vein.

37. Vascular surgery is medically necessary when a vein shows significant insufficiency or reflux of blood flow. This is indicated by the size (diameter) of the vein, because larger veins mean decreased blood flow, as well as actual reflux, meaning blood is flowing in the wrong direction. In either case, vein diameter and reflux are typically diagnosed through ultrasound imaging. In addition, standard medical practice (and common insurance requirements) dictates that the patient typically must try less invasive procedures—such as wearing compression socks or losing weight—typically for three months prior to any surgical intervention is deemed necessary.

Operations of Bellamah and BVC

38. Bellamah started BVC for treating varicose veins in 2014. From 2014 through the present, Bellamah has been and remains the only physician

working at BVC. Other medical personnel employed at BVC included physical assistants, nurses, medical assistants, and sonographers.

39. Bellamah quickly turned BVC into the busiest varicose vein treatment center in Montana. Bellamah was paid over $1.5 million by Medicare in calendar year 2015, which made him the highest paid Medicare vascular surgery provider in Montana.

40. In fact, Bellamah was one of Medicare's highest reimbursed vascular surgery specialists in the western United States. From 2015 through 2019, Bellamah was in the top 95% of all vascular surgery specialists in the western United States for payment by Medicare, and he was the highest paid vascular surgery provider in Montana.

41. This is despite many providers in Montana and other states treating more Medicare beneficiaries than Bellamah. Bellamah performed more vascular surgeries per patient and was, therefore, paid more by Medicare per patient than any other vascular surgery provider in Montana, and he was, again, in the 95th percentile of all vascular surgeons in the western United States. Bellamah was paid by Medicare on average almost $4,000 per patient. In contrast, the next highest vascular surgery provider in Montana was only paid $611 per patient, on average.

Manipulation of Ultrasounds

42. Bellamah and BVC instituted policies and procedures which were designed to maximize the number of patients insurers would cover for surgical procedures. This included posting the vein diameter requirements for different insurers so the sonographers could reference and tailor their results to those requirements when reviewing ultrasounds.

43. Each time a sonographer performed an ultrasound which did not show reflux or a sufficient vein diameter to justify surgical procedures, BVC's policy required a second sonographer to perform a second ultrasound to attempt to find a sufficient vein diameter. The converse was not required, meaning that BVC policy did not require a second sonographer to perform a second ultrasound if the first image was considered sufficient to justify vascular surgery.

44. In order to increase vein diameters, BVC patients were sometimes instructed to exercise their legs, such as by doing squats or walking up and down stairs. Occasionally, BVC employees would apply heat to the legs, such as with a heated blanket, in an attempt to increase vein diameters. These practices were outside the standard medical practice for this field.

45. BVC sonographers were encouraged to measure vein diameters incorrectly. Contrary to standard medical practice of measuring vein diameters

from inside the vein wall to the inside of the opposite vein wall (to measure the true diameter of blood flow), Bellamah and BVC sonographers would measure from outside the vein walls. This would include the vein walls themselves in the measurement, and lead to a falsely increased vein diameter.

46. In addition, BVC sonographers would routinely take the ultrasound image at an oblique, non-perpendicular angle to the vein. This was outside of standard medical practice, which is to take the ultrasound image perpendicular to the vein. As above, this was done to intentionally and falsely increase the apparent diameter of the vein.

47. Finally, Bellamah and BVC sonographers would frequently misread ultrasound results. Waveform artifacts in the ultrasound images were misinterpreted as showing actual reflux, outside of standard medical practice, and would be falsely recorded as reflux in patients' medical records.

48. Bellamah was aware of these ultrasound practices, and that they were outside the standard medical practice for this field. Bellamah personally encouraged BVC sonographers to qualify patients for vascular surgery "by any means necessary."

Medically Unnecessary Vascular Surgeries

49. Ultimately, the ultrasound images taken outside the scope of standard medical practice, and/or which were falsely interpreted, were used to justify surgical procedures which were not medically necessary. Bellamah and BVC submitted claims for payment to Medicare, Medicaid, TRICARE, and CHAMPVA which were based on these false or fraudulent ultrasound images.

50. Bellamah also performed more surgeries per patient than standard medical practice allowed. Bellamah frequently surgically removed or destroyed all possible superficial veins that could be treated in a single patient, including all saphenous veins and multiple perforator veins in each leg. Whereas the common standard of care was to treat an incompetent saphenous vein first and leave perforator veins alone, unless the patient had a venous ulcer or skin change that was fed by a specific perforator vein.

51. In addition, Bellamah frequently split these multiple surgeries into separate procedures on different days, rather than perform all of these surgeries at the same time. By splitting up the surgeries in this fashion, Bellamah increased the payments he received from government health care programs.

Other False Statements in Medical Records

52. In addition to the false or fraudulent ultrasound issues and the overuse of vascular surgeries which were not medically necessary, Bellamah and BVC submitted claims for payment to Medicare, Medicaid, TRICARE, and CHAMPVA based on other false or fraudulent records. Many BVC patient records documented that the patients performed three months of non-invasive treatment, such as using compression socks on the legs, before Bellamah recommended or performed vascular surgeries, when in fact in several instances those statements were not true. Those statements were added by Bellamah or other staff at BVC to justify surgical treatments which would not have been paid by the government health care programs involved absent those false or fraudulent statements.

53. Separately, many BVC medical records state that the beneficiaries experienced pain in their legs and/or that their activities of daily living were impeded, when in fact in several instances those statements were not true. Those statements were added by Bellamah or other staff at BVC to justify surgical treatments which were not medically necessary, and which would not have been paid by the government health care programs involved absent those false or fraudulent statements.

VI. CLAIMS FOR RELIEF

COUNT I
False Claims Act: Presentation of False Claims
31 U.S.C. 3729(a)(1)(A), formerly 31 U.S.C. 3729(a)(1)

54. Paragraphs 1-55 are incorporated by reference as though fully set forth here.

55. Defendants knowingly (as "knowingly" is defined by 31 U.S.C. 3729(b)(1)) presented or caused to be presented false or fraudulent claims for payment or approval to the United States. Specifically, Defendants knowingly submitted false claims to government health care programs such as Medicare, Medicaid, TRICARE, and/or CHAMPVA by submitting claims for ultrasounds which were taken inappropriately and outside standard medical practice.

56. In addition, Defendants knowingly submitted false claims to government health care programs such as Medicare, Medicaid, TRICARE, and/or CHAMPVA by submitting claims for vascular surgeries which were not medically necessary, and/or supported by false or fraudulent medical records. The falsity contained in these claims was material, in that the government health care programs would not have paid the claims had they known the truth.

57. The United States was damaged by these false or fraudulent claims, and paid moneys to Bellamah and BVC that otherwise would not have been paid.

The United States is entitled to three times its damages, the exact amount to be proven at trial, as well as a civil penalty for each false or fraudulent claim submitted to a government health care program such as Medicare, Medicaid, TRICARE, and CHAMPVA.

COUNT 2
False Claims Act: Making or Using False Records or Statements
31 § U.S.C. 3729(a)(1)(B) (formerly 31 U.S.C. 3729(a)(2))

58. Paragraphs 1-55 are incorporated by reference as though fully set forth here.

59. Defendants knowingly (as "knowingly" is defined by 31 U.S.C. 3729(b)(1)) made, used, or caused to be made or used, false records or statements material to false or fraudulent claims paid or approved by the United States. Specifically, Defendants knowingly made false records by taking and measuring ultrasound images inappropriately and outside of standard medical practice. In addition, Defendants knowingly made false records by falsely recording the time frame patients used less invasive means of treatment, and/or by falsely stating patients were in pain or that their activities of daily living were impeded. The falsity in these records was material, in that the government health care programs would not have paid the claims had they known the truth.

60. The United States was damaged by these false records and statements, in that it paid medical claims to Bellamah and BVC that otherwise would not have been paid absent the falsity. The United States is entitled to three times its damages, the exact amount to be proven at trial, as well as a civil penalty for each false record or statement made or used in the submission of a claim to a government health care program.

COUNT 3
Unjust Enrichment

61. Paragraphs 1-55 are incorporated by reference as though fully set forth here.

62. Defendants have received money from Plaintiff United States to which Defendants were not entitled, which unjustly enriched Defendants, and for which Defendants must make restitution. Defendants received such money by claiming and retaining payments from government health care programs such as Medicare, Medicaid, TRICARE, and CHAMPVA for medically unnecessary procedures and treatments. In equity and good conscience, such money belongs to Plaintiff United States.

63. Plaintiff United States is entitled to recover such money or a portion of such money from each defendant in an amount to be determined at trial.

COUNT 4
Payment by Mistake

64. Paragraphs 1-55 are incorporated by reference as though fully set forth here.

65. Plaintiff United States paid money to Defendants as a result of a mistaken understanding. Specifically, Plaintiff United States paid Bellamah and BVC's claims for reimbursement to government health care programs such as Medicare, Medicaid, TRICARE, and CHAMPVA under the mistaken understanding that such claims were for reimbursement for medically necessary procedures or treatments, when in fact they were for reimbursement for medically unnecessary procedures or treatments. Had Plaintiff United States known the truth, it would not have paid such claims. Payment therefore was by mistake.

66. As a result of such mistaken payments, Plaintiff United States has sustained damages from each defendant in an amount to be determined at trial.

VII. REQUEST FOR RELIEF

Plaintiff United States demands judgment as follows:

1. On Counts I and II (False Claims Act), against all Defendants jointly and severally, for the amount of the United States' damages, trebled as required by law, together with the maximum civil penalties allowed by law, costs, post-judgment interest, and such other relief as the Court may deem appropriate;

2. On Count III (Unjust Enrichment), against all Defendants jointly and severally, for an amount equal to the monies that Defendants obtained from the United States without right and by which Defendants have been unjustly enriched, plus costs, pre-and post-judgment interest, and such other relief as the Court may deem appropriate; and,

3. On Count IV (Payment by Mistake), against all Defendants jointly and severally, for an amount equal to the United States' damages plus costs, pre- and post-judgment interest, and such other relief as the Court may deem appropriate.

DATED this 15th day of December, 2021.

LEIF JOHNSON
United States Attorney

/s/ Michael A. Kakuk
Assistant U. S. Attorney
Attorney for Plaintiff